



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration  
New England District

94893d

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 596-7700  
FAX: (781) 596-7896

**WARNING LETTER**  
**NWE-30-04W**

**VIA CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

July 8, 2004

Lyndon Smith, Owner and Manager  
Bounty Seafood  
311 Upper Park Street  
Rockland, ME 04841

Dear Mr. Smith:

We inspected your seafood processing facility, Bounty Seafood, located at 311 Upper Park Street, Rockland, ME on March 10 and March 30, 2004. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your Ready-To Eat (RTE) cooked crabmeat product is adulterated in that the product has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You can find this Act, the seafood HACCP regulation, and the Third Edition to FDA's Fish and Fisheries Products Hazards and Controls Guidance through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The serious deviations observed during the inspection were as follows:

1. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b) and (c). However, your firm did not record monitoring observations at the cook and cold storage critical control points to control the pathogen growth hazard listed in your HACCP plan for cooked crabmeat. Specifically, your cooker log for product cook dates 1/28/04; 1/29/04; 2/3/04; 3/9/04; 3/10/04; and 3/23-26/04 does not contain monitoring records.

2. You must implement the monitoring procedures listed in your HACCP plan for cooked ready-to-eat crabmeat, to comply with 21 CFR 123.6(b). However, your firm did not have a recording thermometer in the cooler as listed in your HACCP plan for cooked ready to eat crabmeat.
3. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for safety of water; cleanliness of food contact surfaces; prevention of cross contamination; maintenance of handwashing and toilet facilities; protection of food and food contact surfaces from adulterants; proper labeling, storage and use of toxic compounds; control of employee health conditions and exclusion of pests from the food plant required for processing cooked RTE crabmeat. Furthermore, as noted in the Amended FDA-483 issued to you on March 30, 2004, we observed sanitation deficiencies during the inspection of your firm.

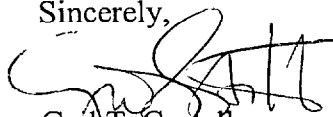
We may take further action if you do not promptly correct the above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct the deviations. You should include in your response any documentation, such as your revised HACCP plan, copies of completed monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with all statutes and regulations enforced by the agency. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Ann Simoneau, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Simoneau at (781) 596-7732.

Sincerely,



Gail T. Costello  
District Director  
New England District Office